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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,663	11/27/2001	Toshiaki Sasaki	00862.022452.	8052
5514 7590 05/18/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK NY 10112			EXAMINER	
			NAJARIAN, LENA	
NEW YORK, NY 10112		ART UNIT	PAPER NUMBER	
			3686	
			MAIL DATE	DELIVERY MODE
			05/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	09/993,663	SASAKI ET AL.				
Office Action Summary	Examiner	Art Unit				
	LENA NAJARIAN	3686				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>20 October 2008</u> .						
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3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1,3-8,10-14,100,101 and 103</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,3-8,10-14,100,101 and 103</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) 🔯 Information Disclosure Statement(s) (PTO/SB/08) 5) 🔲 Notice of Informal Patent Application						
Paper No(s)/Mail Date <u>20090428</u> . 6)						

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to the communication filed 10/20/08. No claims have been amended. Claims 1, 3-8, 10-14, 100, 101, and 103 remain pending.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1, 3, 4, 6-8, 10, 11, 13, 14, 100, and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne (US 2005/0060198 A1) in view of Reuss et al. (US 6,406,426 B1).
- (A) As per claim 8, Bayne discloses a health management method of managing health of each patient, including the steps of:

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providing a portable terminal carried by a user with a display screen, radio communication means for accessing a predetermined radio communication network, storage means storing personal information of the user, and an input/output device for supporting health management for the user, (Bayne, Abstract; ¶ 36, 39-41); and an emergency notification switch to enter an emergency notification mode, (Bayne, ¶ 32, 78).

providing a database for communicating with each portable terminal with personal information storage means storing the personal information about each user carrying the portable terminal, medical information storage means storing information about a medical facility, a drugstore, a medicine, and the input/output device, and communication means for communicating with the portable terminal through the radio communication network, (Bayne, Abstract; ¶ 36, 45-47, 96);

transmitting part of the personal information stored in the storage means by the radio communication means when starting to communicate with the database, (Bayne, Abstract; ¶ 36, 45);

identifying using the database, the user of the portable terminal by collating the part of the information transmitted from the radio communication means with information stored in the personal information storage means, (Bayne, Abstract; ¶ 36, 45); and activating an emergency handling means which provides either communication with a medical facility whose information is stored in the medical information storage

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means or information stored in the medical information storage means, which is necessary for the identified user (Bayne, ¶ 32, 50, 78), and

wherein the personal information includes information of a clinical chart of the user and prescription, (Bayne ¶ 93).

Bayne does not disclose that the portable terminal carried by the patient enters an emergency notification mode.

Reuss discloses that the portable terminal carried by the patient enters an emergency notification mode (see col. 3, line 61 – col. 4, line 7 and col. 6, line 60 – col. 7, line 26 of Reuss).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Reuss within Bayne. The motivation for doing so would have been to provide alert condition and status data to remote caregivers (col. 6, lines 60-62 of Reuss).

- (B) As per claim 10, Bayne discloses a method wherein the radio communication means and the communication means perform encryption/decryption in accordance with a predetermined scheme in transmitting/receiving at least part of the personal information, (Bayne, ¶ 45).
- (C) As per claim 11, Bayne discloses a method wherein the portable terminal acquires position information of the terminal, and information about a route to a suitable medical facility or drugstore is displayed on the display screen on the basis of the position information, (Bayne, ¶ 39, 40, 50).

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(D) As per claim 13, Bayne discloses a method wherein in the database, when no information is transmitted a predetermined period of time after a specific signal is transmitted from the radio communication means, communication is made to an emergency facility, (Bayne, ¶ 77-84) (disclosing automatic emergency call initiation).

- (E) As per claim 14, Bayne discloses a method wherein part of the information includes information about biometrical characteristics of the patient, (Bayne ¶ 93).
- (F) As per claims 1, 3, 4, 6, and 7, these system claims contain the same or similar limitations as the corresponding method claims 8, 10, 11, 13, 14, respectively, and are therefore rejected for the same reasons given above.
- (G) As per claim 100, Bayne discloses an information provision method for providing medical information about health, a medical treatment or a medicine from a database, comprising steps of:

receiving, from a portable terminal through a network, user information stored in the portable terminal and an emergency notification for entering an emergency notification mode, (Bayne, ¶ 32, 50, 78);

wherein the personal information includes information of a clinical chart of the user and prescription, (Bayne ¶ 93).

identifying a user of the portable terminal by collating the user information transmitted from the portable terminal with personal information stored in the database(Bayne, ¶ 32, 50, 78); and

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providing either communication with a medical facility or the medical information stored in the database to the portable terminal of the identified user in the emergency notification mode, (Bayne, ¶ 32, 50, 78).

Bayne does not disclose that the portable terminal carried by the patient enters an emergency notification mode.

Reuss discloses that the portable terminal carried by the patient enters an emergency notification mode (see col. 3, line 61 – col. 4, line 7 and col. 6, line 60 – col. 7, line 26 of Reuss).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Reuss within Bayne. The motivation for doing so would have been to provide alert condition and status data to remote caregivers (col. 6, lines 60-62 of Reuss).

- (H) As per claim 103, Bayne discloses an information provision method wherein the medical information is route information about a suitable medical facility or drugstore for the identified patient, (Bayne, ¶ 39, 40, 50).
- 5. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne, (U.S. 2005/0060198), in view of Reuss et al. (US 6,406,426 B1), and further in view of Mishelevich et al., (U.S. 5,363,842).
- (A) As per claim 12, Bayne discloses a health management method of managing health of each patient, including the steps of:

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providing a portable terminal carried by a user with a display screen, radio communication means for accessing a predetermined radio communication network, storage means storing personal information of the user, and an input/output device for supporting health management for the user, (Bayne, Abstract; ¶ 36, 39-41); and an emergency notification switch to enter an emergency notification mode, (Bayne, ¶ 32, 78).

providing a database for communicating with each portable terminal with personal information storage means storing the personal information about each user carrying the portable terminal, medical information storage means storing information about a medical facility, a drugstore, a medicine, and the input/output device, and communication means for communicating with the portable terminal through the radio communication network, (Bayne, Abstract; ¶ 36, 45-47, 96);

transmitting part of the personal information stored in the storage means by the radio communication means when starting to communicate with the database, (Bayne, Abstract; ¶ 36, 45);

identifying using the database, the user of the portable terminal by collating the part of the information transmitted from the radio communication means with information stored in the personal information storage means, (Bayne, Abstract; ¶ 36, 45); and

activating an emergency handling means which provides either communication with a medical facility whose information is stored in the medical information storage means or information stored in the medical information storage means, which is

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necessary for the identified user, in accordance with information transmitted from said radio communication means (Bayne, ¶ 32, 50, 78),

and wherein the personal information includes information of a clinical chart of the patient and a prescription (Bayne ¶ 93).

Bayne does not disclose that the portable terminal carried by the patient enters an emergency notification mode.

Reuss discloses that the portable terminal carried by the patient enters an emergency notification mode (see col. 3, line 61 – col. 4, line 7 and col. 6, line 60 – col. 7, line 26 of Reuss).

Bayne and Reuss fail to disclose a method wherein the input/output device is an inhaler for discharging a medicine in the form of fine droplets to make the user inhale the droplets, and the information about the input/output device includes information about handling of the inhaler. However, such a method is well known in the art as evidenced by Mishelevich, (Mishelevich, Abstract, col. 4, line 35 - col. 5, line 18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the aforementioned features of Mishelevich and Reuss within Bayne. The motivation would have been to create a hand-held inhaler device to provide information to both patient and healthcare professional regarding correct usage, actuation, flow rate, and duration, (Mishelevich, col. 4, lines 16-32) and to provide alert condition and status data to remote caregivers (col. 6, lines 60-62 of Reuss).

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(B) As per claim 5, the system claim contains the same or similar limitations as the corresponding method claim 12. As such, claim 5 is rejected for the same reasons given for claim 12 above.

6. Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne, (U.S. 2005/0060198), in view of Reuss et al. (US 6,406,426 B1), in view of Mishelevich et al., (U.S. 5,363,842), and further in view of Voges, (U.S. 5,894,841). (A) As per claim 101, the collective system of Bayne, Reuss, and Mishelevich fails to disclose a method wherein said portable terminal includes an inhaler which discharges a medicine on the basis of an ink-jet scheme using heat, (Voges, Abstract; col. 4, lines 34-67, col. 5, lines 20-25).

The statement of obviousness and motivation to combine Bayne, Reuss, and the inhaler of Mishelevich is as provided in the rejection of claim 12 and incorporated herein.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the ink-jet system of Voges to the collective system of Bayne, Reuss, and Mishelevich. The motivation would have been to provide precise dose control, (Voges, col. 2, lines 7-9).

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Response to Arguments

7. Applicant's arguments with respect to claims 1, 5, 8, 12, 100, and 101 have been considered but are most in view of the new ground(s) of rejection.

Conclusion

- 8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday Friday, 9:30 am 6:00 pm.
- 10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./ Examiner, Art Unit 3686 In 5/14/09

> /Gerald J. O'Connor/ Supervisory Patent Examiner Group Art Unit 3686